Exposure Assessment Approaches For Chemicals Used As Soil Fumigants

Consideration Of The Fumigant Exposure Modeling System (FEMS) - A Case Study With Metam-Sodium

Presented To The FIFRA Science Advisory Panel By:

U.S. EPA Office Of Pesticide Programs
Health Effects Division

Presented On:

August 26/27, 2004

1 INTRODUCTION

On August 24-25, August 26-27, and September 9-10, 2004, the FIFRA Scientific Advisory Panel (SAP) will hold three separate meetings to consider and review three fumigant bystander exposure models. At the August 24-25 meeting the SAP will review the Probabilistic Exposure and Risk model for FUMigants (PERFUM) using iodomethane as a case study. On August 26-27, the SAP will review the Fumigant Exposure Modeling System (FEMS) using metam sodium as a case study. On September 9-10, the SAP will review the SOil Fumigant Exposure Assessment system (SOFEA(copyright)) using telone as a case study. In preparing for these meeting, preparation of this document, and development of questions for the Panel, the Agency has worked closely with scientists from the California Department of Pesticide Regulation who have significant experience with inhalation exposure modeling.

The purpose of this document is to provide general background information for the FIFRA Science Advisory Panel (SAP) meeting pertaining to the evaluation of the *Fumigant Exposure Modeling System* (or FEMS). FEMS represents a potential evolution of the Agency's current methodology for calculating exposures to bystanders who can be exposed by being in close proximity to fields treated with soil fumigants prior to planting crops such as strawberries or tomatoes. FEMS was developed by the registrants (i.e., manufacturers or licensees) of the soil fumigant metam-sodium. At the upcoming SAP meeting, a detailed FEMS case study will be presented based specifically on metam-sodium data for illustrative purposes by its developers. More specific background materials pertaining to the theories and code included in FEMS than there are in this document, are available in the following which has been provided by its developers for consideration (available at: http://www.epa.gov/oscpmont/sap/2004/#top).

Background Document: Fumigant Emissions Modeling System, Sullivan, Hlinka, and Holdsworth, July, 2004

The Agency has a broad range of goals for this meeting in that it wishes to evaluate the methodologies inherent in FEMS from a general perspective to (1) determine their scientific validity and (2) determine if there is any general applicability for evaluating risks associated with many or all soil fumigants. There are three key criteria that the Agency considers when considering the integration of a model into its risk assessment process and these include: (1) public availability; (2) peer review for scientific validity; and (3) adherence to Agency guidelines for model development. In order to have FEMS considered by the Agency and by the SAP the developers of FEMS have agreed to make it available for public use.

The Agency is currently involved in the development of a comparative risk assessment for 6 pesticides that are used for soil fumigation purposes. Some of these chemicals also have other allowed uses but, for clarity, the discussion within this document focuses only on soil fumigation since it is of key concern and it accounts for the majority of the annual usage for each chemical. The chemicals which are included in this assessment are: chloropicrin, dazomet, iodomethane (i.e., methyl iodide), methyl bromide, metam-sodium (or other salts), and telone (or 1,3-dichloropropene). Each of these chemicals (or their breakdown products, metam-sodium and dazomet both emit MITC or methyl isothiocyanate which is the volatile component) are extremely volatile especially when compared to most common pesticides. Most common pesticides are considered semi-volatile organic chemicals (or SVOCs) while soil fumigants would be considered volatile organic chemicals (or VOCs). The volatility of each material is the key characteristic associated with their use and achieving a satisfactory measure of efficacy. This volatility, however, can lead to a potential for human exposures because it leads to transport away from targeted application areas to non-target receptors such as nearby human populations.

The Agency's goal for this risk assessment is to quantify emissions from treated fields and use them as a determinant of human risks. Emissions from treated fields can be categorized in two ways including:

(1) **Known Source:** include those directly associated with a single application (or series of associated applications) adjacent to a receptor where the source and emissions specific to the application(s) can be quantified. An example would be treating a field that borders a residential subdivision then defining the amount of off-target residue movement associated with that specific application. The concept of a buffer zone as a risk management tool is commonly associated with these situations.

(2) **Multiple Source (Ambient Air):** includes those associated with multiple applications or general use within a region where many non-quantifiable applications can possibly contribute to overall exposure levels. In general, ambient exposures within a region cannot be easily attributed to specific application events. An example of this type of emission might be those air concentrations measured at a school location when the school is located within a growing region where fumigants are extensively used. The concept of a localized use cap as a risk management tool is commonly associated with these types of exposures.

A discussion and quantification of each type of emission will ultimately be included in the Agency risk assessment for soil fumigants, however, the focus of this document and the upcoming SAP meeting is the *Fumigant Exposure Modeling System* (or FEMS) which is primarily intended to quantify emissions from single, known applications (e.g., treating a field with a subdivision immediately adjacent to its perimeter). [Note: The FEMS prototype model submitted for review does not automatically address multiple field scenarios, but can be run on a custom basis to evaluate multiple fields that are independent or part of a planned application sequence of a large field.]

In order to quantify emissions from single application events, the Agency currently uses an approach that first considered the monitoring data available for each of the six soil fumigants along with a deterministic modeling approach. It was clear that given the breadth of the uses associated with soil fumigants (e.g., varied atmospheric conditions, application methods, and emission reduction technologies such as tarping or watering in) that use of monitoring data alone for risk assessment purposes was limited by the relatively small number of samples which can reasonably be generated for different times after treatment, distances from the application site, and use patterns. This conclusion led to the development of the Agency's current modeling approach and the possible evolution of that approach represented by FEMS. The model-based approach considers temporal and spatial factors, extrapolating from available monitoring data, thus providing an estimate of the range of exposures which are possible at different times and locations when input parameters are varied. Use of a model and monitoring data are, however, intertwined in a general sense because monitoring data are used as the basis for estimating emission factors used in the model.

The Agency is currently using a deterministic modeling approach for defining air concentration gradients downwind of applications for each chemical. In this approach, the Agency has based its analysis on a standardized set of meteorological conditions intended to represent a stable atmosphere and unidirectional wind patterns that is intended to provide high-end estimates of exposure. To this end, the Agency has developed a methodology based on the Office of Air model ISC3 (Industrial Source Complex Model) that is routinely used for regulatory purposes. ISC3 is a steady-state Gaussian plume model which can be used to assess pollutant concentrations from a wide variety of sources. ISC3 is a publically available system and can be downloaded from the Agency (http://www.epa.gov/scram001/tt22.htm#isc).

Stakeholders have commented to the Agency a belief that these standardized meteorological conditions are not representative of actual atmospheric conditions where soil fumigants are used and therefore solely provide screening level results which are inadequate for risk mitigation decision making purposes. To this end, the metam-sodium registrants have submitted to the Agency the FEMS model for consideration. FEMS integrates actual meteorological data into ISC3 which then provides for the calculation of multi-directional air concentration gradients based on these data. As with the Agency's approach, these resulting concentration gradients would ultimately be used as a determinant of human health risks. Additionally, it should also be noted that the FEMS model uses a probability based approach for integrating emission and application frequency data which are unique to this system.

This document describes the Agency's current approach for model use in *Section 2: Summary Of Current Modeling Approach*. *Section 3: Overview of Fumigant Exposure Modeling System (FEMS)* provides a brief summary of the approaches that have been incorporated into the system. *Section 4: Charge To Panel* details the specific questions pertaining to the use of FEMS which the Agency would like the SAP panel to address in its deliberations.

2 SUMMARY OF CURRENT MODELING APPROACH

The goals of the Agency in its fumigant assessment are to develop health protective measures of risk for populations in close proximity to fields that have been treated with soil fumigants as well as to explain and reduce, whenever possible, the uncertainties associated with these analyses. In order to achieve these goals, the Agency first considered monitoring data specific to each chemical but due to the limitations of those data and the flexibility that modeling represents have focused on model results as the key predictor of risks.

The Agency's current exposure assessment approach is based on a deterministic use of the Agency's Industrial Source Complex Model (ISC) which is routinely used by the Office of Air for regulatory decision making purposes. It is available from the following website at the *Technology Transfer Network Support Center for Regulatory Air Models (or SCRAM)* (http://www.epa.gov/scram001/tt22.htm#isc). ISC is a steady-state Gaussian plume model which can be used to assess pollutant concentrations from a wide variety of sources associated with an industrial complex or from other types of sources such as an agricultural field in this case. This model can account for the following: settling and dry deposition of particles; downwash; point, area, line, and volume sources; plume rise as a function of downwind distance; separation of point sources; and limited terrain adjustment. ISC can operate in both long-term and short-term modes but has been used in the short-term mode for the purposes of this assessment.

The Agency's current approach is summarized herein. *Section 2.1 Input Variables And Settings Used For ISC Calculations* describes the current modeling approaches used by the Agency including a description of the specific inputs and ISC settings used for the calculations. *Section 2.2 Outputs Based on Current Modeling Approach* provides examples of the outputs from ISC that might be presented for consideration by risk managers. To ensure a level of consistency in the evaluation of the FEMS model, the examples presented below to describe the current Agency methodology are also based on a case study using metam-sodium.

2.1 Input Variables And Settings Used For ISC Calculations

In order to define concentration gradients associated with the use of soil fumigants, which are ultimately determinants of exposure, the Agency utilized ISC by equating treated agricultural fields to an area source coupled with inputs that reflected a range of potential atmospheric conditions and application equipment/techniques used for the different fumigant chemicals. In order to do this, the Agency considered various combinations of four categories of input variables including:

- Field Size;
- Atmospheric Conditions;
- Application Equipment and Control Technologies; and
- Field Emissions Associated With Application Equipment and Control Technology.

[Note: As a convention, the Agency has used similar input variables for all of the 6 soil fumigant chemicals wherever possible. This allows for an easier determination of the relative risks amongst the 6 soil fumigants. Some input factors such as emission data, however, are by nature chemical-specific and have been treated as such in analyses completed by the Agency. This is the rationale behind providing a separate section which details how the emission data were analyzed for metam-sodium.]

Field Size: The Agency generically is using a range of field sizes for single application events from 1 acre up through 40 acres. Specifically, the Agency based its calculations on field sizes of 1, 5, 10, 20, and 40 acres. It is believed that most distinct soil fumigation application events will be within this range of areas treated. It is also acknowledged larger fields could be treated on a single day. Results could easily be scaled to those larger acreages if needed. These field sizes are also essentially consistent with analyses completed by the California Department of Pesticide Regulation which allows for easy comparison with their results. Field geometry can also impact the results of ISC modeling. For ease, the Agency has by convention completed all of its analyses based on the use of square fields.

Atmospheric Conditions: ISC calculates downwind air concentrations using hourly meteorological conditions, that include wind speed and atmospheric stability (for a more detailed discussion of stability see http://www.epa.gov/scram001/userg/relat/pcramtd.pdf). The higher the letter associated with a stability class the more stable the atmosphere becomes. The lower the wind speed and the more stable the environment, the higher the air concentrations are going to be close to a treated area (or source). Conversely, if wind speed increases or the atmosphere is less stable, then air concentrations are lowered in proximity to the treated area thereby lowering the potential for exposure. Atmospheric stability is essentially a measure of how turbulent the atmosphere is at any given time. Stability is affected by solar radiation, wind speed, cloud cover, and temperature among other factors. Instability in the atmosphere increases the movement of airborne residues because they are more readily pushed up into the atmosphere and moved away from the source thereby lowering concentrations in close proximity to the source (e.g., treated field).

In order to simplify modeling the transport of soil fumigant vapors from a treated field, a single wind direction, wind speed, and stability category are used for a given duration of concern (i.e., 1 to 24 hours for metam-sodium and dazomet, 24 hours for others). The Agency has decided to present a series of results based on a range of possible, and plausible, meteorological conditions to allow for a better characterization of risks compared to just completing the analyses based on a single set of meteorological conditions. The different conditions considered by the Agency are presented in Table 1.

For comparative purposes, the California Department of Pesticide Regulation, in its determination of buffer zones for methyl bromide, based its decisions upon a wind speed of 1.4 m/s and a class C atmospheric stability value for a 24-hour period. These assumptions are more suitable to daytime conditions than to nighttime periods during which wind speeds could be lower and the atmosphere more stable. We believe these values provide higher-end air concentrations. [Note: This is supported by an analysis methyl bromide buffer zones by DPR available at: www.cdpr.ca.gov/docs/dprdocs/methbrom/mebrmenu.htm.]

Table 1: Meteorological Combinations Used in ISC Calculations		
Wind Speed (mph)	**Wind Speed (meters/second)**	**Stability Category#**
2.25^	1.0^	F^
2.25	1.0	D
3.1*	1.4*	C*
4	1.8	C
5	2.2	C
6	2.7	C
7	3.1	C
8	3.6	C
9	4.0	C
10	4.5	C
10	4.5	B

= The lower the assigned "letter" the less stable the atmosphere. Categories A to D are generally seen in daylight conditions. Nighttime conditions are generally even more stable than even the most stable daylight conditions.
^ =Conditions only used for 1 hour exposure duration.
* = Conditions used in DPR assessment and risk management decisions for methyl bromide.

Application Equipment and Control Technologies: Application equipment and control technologies are varied and depend on many factors including the environmental fate characteristics of the chemical, terrain where the chemical is being used, economic considerations, and other agricultural practices. Application equipment can take many forms but applications typically involve the use of some sort of probe that is used to inject material beneath the surface of the soil, a broadcast application of a liquid solution or solid material across the surface of a treated area, or the delivery of chemicals through some sort of plumbed system throughout the treated area (e.g., some chemicals are delivered via irrigation water).

Along with the various application methods there are a number of control technologies that are intended to minimize the emissions from treated fields. These can take many forms but essentially involve one of three basic techniques that include: (1) change in injection depth and probe design; (2) use of tarping or bedding techniques; and (3) watering-in.

Ultimately, the goal of the Agency is to codify different combinations of application methods and control technologies in order to have these serve as a systematic basis for risk assessments. The ability to do this, however, varies depending upon the data available for each chemical. In some cases, such as methyl bromide, there is a preponderance of data that allows for characterization based on a large number of possibilities as described by the California Department of Pesticide Regulations in its permit conditions which are presented on their website (http://www.cdpr.ca.gov/docs/legbills/mebrbuffer.pdf).

The situation with metam-sodium differs somewhat, however, in that DPR currently has only proposed permit conditions for its use. Based on the available data, the Agency has developed categories of application methods associated with metam-sodium use (Table 2). These include 3 basic categories of application equipment with 2 different exposure reduction technologies associated with each. This list is by no means inclusive of the ways that metam-sodium might possibly be applied in agriculture but data are not available to adequately quantify other types of application methods or emission reduction technologies. Hence, all analyses that were completed were based on these categories.

Table 2: Summary Of Application Methods For Metam-Sodium

Application Method	Emission Reduction Technology*	Combination #
Sprinkler Irrigation	Standard Water Seal	1
	Intermittent Water Seal	2
Shank Injection	Standard Water Seal	3
	Intermittent Water Seal	4
Drip Irrigation	Tarped	5
	Untarped	6

*Standard Water Seal: a single application of water directly after the pesticide has been applied, to seal the surface.
* Intermittent Water Seal: An application of water directly after the pesticide has been applied, to seal the surface, followed by application of additional water (in one or two sessions) before late evening on the day of application.

Field Emissions Associated With Application Equipment and Control Technology: Emissions from treated fields are generally characterized as the amount of residues that are offgassing from a unit area per unit time. Emissions quantified in this manner are referred to as flux (μg/m^2-s). Flux rates are specific to the conditions of the field experiment for which they were generated but can be used in a generic sense by normalizing the data to the application rate of concern which was 320 pounds per acre (i.e., the maximum application rate). Flux rates were calculated using the back-calculation method with ISC. The ISC back-calculation method estimates flux rates by extrapolating from the available field air monitoring data, assuming a Gaussian plume distribution, to estimate the flux rate. The normalized flux rates which were determined for metam-sodium are summarized below in Table 3.

Table 3: Summary Of Normalized MITC Flux Rates Associated With Metam-Sodium Applications

Application Method	Emission Reduction Technology	24 Hour Flux Rates (μg/m^2 - s)	Combination #
Sprinkler Irrigation	Standard Seal	98	1
	Intermittent Seal	29	2
Shank Injection	Standard Seal	37	3
	Intermittent Seal	16	4
Drip Irrigation	Tarped	7	5
	Untarped	5	6

Note: These values are subject to change as the Agency was finalizing these calculations during the time this document was prepared. Detailed information concerning these flux calculations will be presented by the Agency at the SAP meeting during introductory remarks.

Other Settings/Parameters: Along with the input variables described above that have been considered by the Agency in this assessment there are other parameters (or settings) that must be defined in order to complete an ISC analysis. These parameters include (see Figure 1):

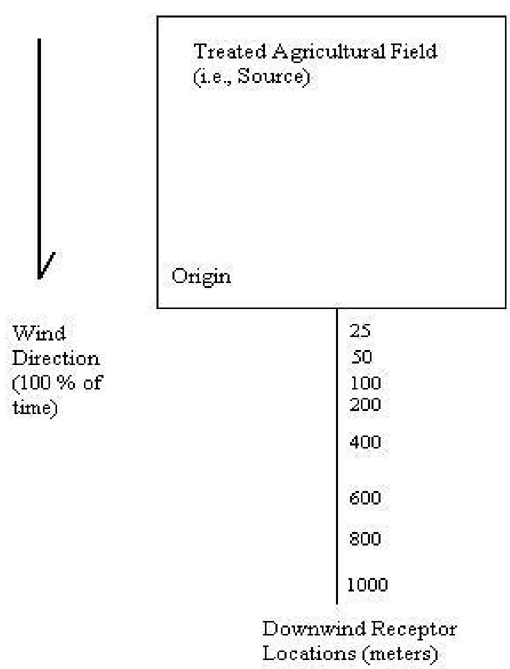
- Rural conditions are used;
- Mixing height 692 m for rural settings (based on DPR analysis);
- Receptor height at ground level (similar to DPR analysis);
- Source (i.e., the treated field) is treated as an area source;
- Source (i.e., the treated field) is square oriented in north/south direction;
- Grid origin is SW corner of field;

- Receptors are centerline of field to the south, buffers are from edge of field;
- Release height is 0 meters;
- Flux rates determined from monitoring data using ISC-based back calculation method as no direct measurements of flux were available for this analysis (i.e., sometimes referred to as indirect flux calculation method);
- Deposition is not accounted for and is expected to be minimal due to volatility of chemical; and
- Standard regulatory default options as defined in ISC User's Guide Volume 1 have been used.

2.2 Outputs Based on Current Modeling Approach

Examples of the kinds of outputs which can be generated by ISC based on inputs similar to those described above are presented in this section. For the purposes of this example, the outputs represent 24 hour average concentrations at selected downwind receptor points. The receptor points are illustrated in Figure 1 along with the unidirectional nature of the meteorological conditions (i.e., wind direction) upon which the assessment is based.

Figure 1: ISC Source & Receptor Grid - Std. Analysis



The results based on the Agency's methodology were calculated using a similar test case as that included as a case study in the background document entitled:

Background Document: Fumigant Emissions Modeling System, Sullivan, Hlinka, and Holdsworth, July 19, 2004

This document is available at (http://www.epa.gov/oscpmont/sap/2004/#top). The test case which was evaluated considered the exposures of individuals surrounding a field that had been treated via chemigation coupled with intermittent water sealing. For comparative purposes, the Agency has summarized the results based on its deterministic approach for this scenario below. These results include air concentrations (μg/m^3) at selected receptor points downwind for a variety of meteorological conditions (Table 4). The conditions considered in this analysis range from a stable atmosphere conducive to higher concentrations in close proximity to treated areas to conditions that are much less stable which lead to lower concentrations in proximity to treated areas.

Table 4: ISC Calculated Air Concentrations At Selected Distances Downwind (μg/m^3) For Pre-Plant Agricultural Field Fumigations

ER	Fld Size (A)	DW Dist. (M)	Air Concentrations At Differing Meteorological Conditions									
			1 m/s 2.3 mph	1.4 m/s 3.1 mph	1.8 m/s 4 mph	2.2 m/s 5 mph	2.7 m/s 6 mph	3.1 m/s 7 mph	3.6 m/s 8 mph	4.0 m/s 9 mph	4.5 m/s 10 mph	4.5 m/s 10 mph
			Stab D	Stab C	Stab C	Stab C	Stab C	Stab C	Stab C	Stab C	Stab C	Stab B
0.07	1	25	573	264	206	168	137	119	103	93	82	58
		100	395	178	138	113	93	80	69	62	55	37
		500	253	107	83	68	55	48	42	37	33	20
		1000	16	4.0	3.1	2.5	2.1	1.8	1.6	1.4	1.2	0.50
		2500	4.1	0.8	0.6	0.5	0.4	0.4	0.3	0.3	0.2	0.08
		5000	1.4	0.2	0.2	0.1	0.1	0.1	0.09	0.08	0.07	0.02
	40	25	1431	634	494	404	329	287	247	222	198	137
		100	1165	507	394	323	263	229	197	177	158	109
		500	898	384	299	245	199	174	149	134	120	81
		1000	255	84	65	53	43	38	33	29	26	12
		2500	118	25	20	16	13	11	10	9.8	7.8	2.6
		5000	50	8.2	6.4	5.2	4.2	3.7	3.2	2.9	2.5	0.9

Note: ER = emission rate which defines flux interms of the percentage of the amount applied. The emission rate of 7 percent or 0.07 for this application method was calculated by dividing the flux rate of 29 μg/meter squared -second by the application rate of 320 pounds/acre/day after conversion to similar units and adjustment of the flux rate to a 24 hour value.

The air concentrations presented in Table 4 would then be used to calculate a risk estimate for each condition. The Agency uses *Margins of Exposure* to represent non-cancer risks which are calculated using the following formula:

$$MOE = \frac{HEC\ (\mu g/m^3)}{Air\ Concentration\ (\mu g/m^3)}$$

Where:

MOE	=	Margin of exposure, value used to represent risk or how close a chemical exposure is to being a concern (unitless);
Air Concentration	=	The concentration in air to which an individual could be exposed ($\mu g/m^3$); and
HEC	=	Human equivalent concentration is the air concentration of a toxicant at a level at which an effect might occur (e.g., NOAEL or LOAEL) after it has been adjusted to pharmacokinetic differences between the test animal species and humans.

In the FEMS case study 6 "threshold" HEC values were used for the purposes of calculating simulated risk estimates that ranged from 25 to 750 $\mu g/m^3$. These do not represent the actual HECs or "thresholds" being considered by the Agency at this point and were only used for illustrative purposes. The Agency wishes to focus discussion at the SAP meeting on the methodologies contained in FEMS that could potentially lead to an evolution in the manner in which the Agency calculates exposure concentrations such as in Table 4 and not on other risk assessment related issues specific to the metam-sodium case study example. As such, the Agency has not included any risk estimates in this document for the case study.

3 OVERVIEW OF FUMIGANT EXPOSURE MODELING SYSTEM (FEMS)

The *Fumigant Exposure Modeling System (FEMS)* is a modeling tool that could potentially represent an evolution in the manner in which the Agency calculates exposures from soil fumigants. It is the methodologies included in FEMS that the Agency wishes the SAP panel to consider in its deliberations. This section contains a very brief overview of the FEMS system and how the outputs might differ from those generated using the current Agency approach for calculating exposures. Definitive discussions of FEMS can be found in the following (http://www.epa.gov/oscpmont/sap/2004/#top).

Background Document: Fumigant Emissions Modeling System, Sullivan, Hlinka, and Holdsworth, July, 2004

The purpose of this discussion is to provide readers with a way to easily contrast the Agency approach and the approaches included in FEMS. Much of the discussion in this section and the graphics included herein are excerpted directly from the above document. It should also be noted that the FEMS developers used data specific to the soil fumigant, metam-sodium, as the basis for the case-study included in this document (i.e., exposures were evaluated for a chemigation application with intermittent water sealing in the case study). The Agency believes that the methods applied in this analysis have generic applicability to all fumigants and wishes that FEMS be considered in this manner yet keeping in mind that some of the inputs used for this analysis have to be specific to metam-sodium in order to complete the case study analysis.

The FEMS model was developed with three critical design considerations in mind including: (1) the intermittent use pattern for soil fumigants; (2) the variability associated with emissions during a daily cycle; and (3) the need to evaluate uncertainty associated with the input parameters throughout a modeling analysis. FEMS is based on EPA models (ISCST3 and TOXST). A Monte Carlo-based interface is used to account for uncertainty in the emission rates and the measured meteorological inputs to the modeling. Monitoring data are used to empirically estimate the best fit and distribution of emissions rates typically as a function of 4-hour time blocks, starting at the time of fumigant application, and extending for 96 hours. FEMS evaluates distances from the edge of a treated field that are needed to reach user-defined endpoints. The intermediate outputs from FEMS also can be processed to display distributions of exposures as a function of distance from the edge of the field. FEMS, in short, provides a probabilistic interface to support data entry and post-processing for ISCST3 and TOXST.

FEMS was developed with agricultural fumigant risk characterization in mind so many of its design features are specific to the needs associated with completing an exposure assessment for agricultural fumigants. FEMS may be more compatible with the source characteristics of agricultural fumigants than routine application of models such as the Agency's current stand alone use of ISCST3 because it contains the means to address factors unique to the methods used to apply them in the field. It also offers flexibility to consider other inputs which may be more refined than those used in the current Agency approach. For example, FEMS can consider the frequency and duration of exposure and model averaging time with less resources than in the deterministic approach. FEMS can also consider multiple field scenarios on an independent or planned, sequential basis as well as consider the variability and uncertainty of this complex source through the use of empirical emissions distributions.

Specifically, in the case study developed based on metam-sodium, the following options/inputs were considered:

- 19.8 acre field (100 by 800 meters);
- Receptor grid (50, 100, 150, 200, 250, 300, 400, 500, 1000 meters);
- 5,000 simulations;
- Emissions, wind speed and direction randomized;
- Stability - non-randomized;
- Ambient concentrations only;
- 1 application/year;
- 4-days of offgassing;
- 4-hour averaging time;
- 100 percent maximum application rate;
- 1.49 times/year above concentration threshold;
- 5 years of meteorological data from Fresno, California;
- Latitude 30 degrees & longitude 110 degrees; and
- Time zone 8 (west coast).

The following graphically describe a number of issues that were considered in the development of FEMS, analysis of the data, interpretation of the results compared to the current Agency practice. Figure 2 provides a comparison of emission rates from fields treated via chemigation between standard and intermittent sealing methods. This figure also illustrates diurnal (day/night) variability in emissions and a general decline in air concentrations over time.

Figure 2

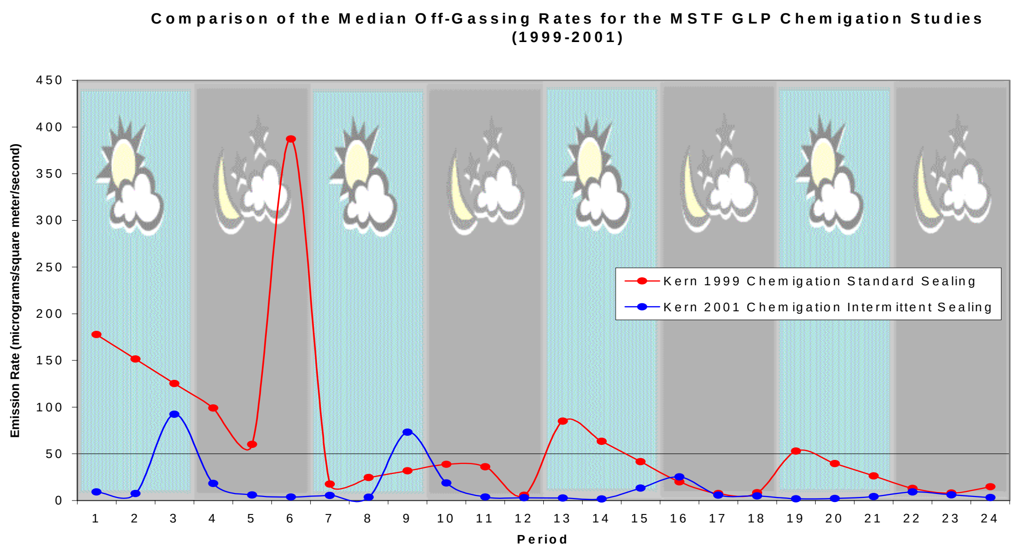
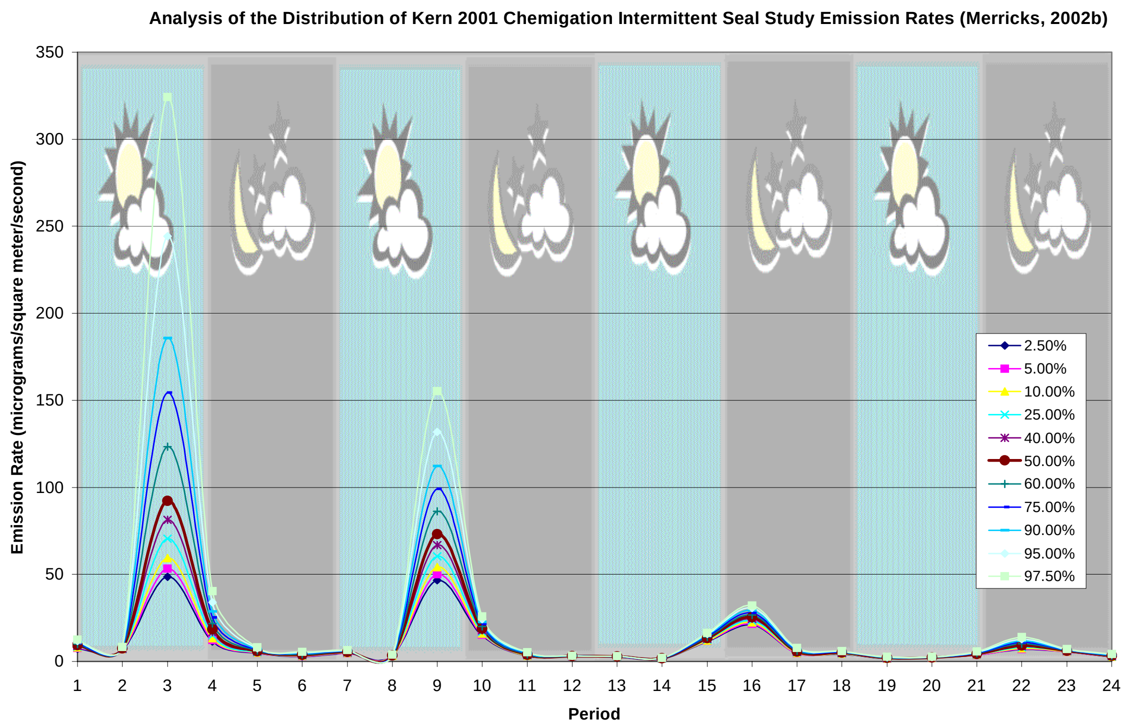


Figure 3 provides a distributional analysis of the intermittent sealing data presented in Figure 2 ranging from the 2.5 to 97.5th percentile.

Figure 3



A sensitivity analysis was conducted for the case study scenario. The conclusions of this analysis were that the uncertainty in the inputs can be represented by independent probabilistic analysis. In addition, it was shown that the emission term accounts for nearly two-thirds of the variance in concentration. Atmospheric stability accounts for approximately another 5 percent, which totals approximately 70 percent of the variance as being attributable to these two factors. Figure 4 provides a scatter plot analysis that was completed which compared emission rate and output concentrations.

Finally, the results of a FEMS analysis (based on a “threshold” concentration of 100 $\mu g/m^3$) are illustrated in Figure 5. This figure clearly illustrates the differences in the FEMS approach compared to that of the Agency when it is compared with Figure 1. The isopleths in Figure 5 are in meters from the treated field.

Figure 4

Concentrations Vs. Emissions Scatterplot

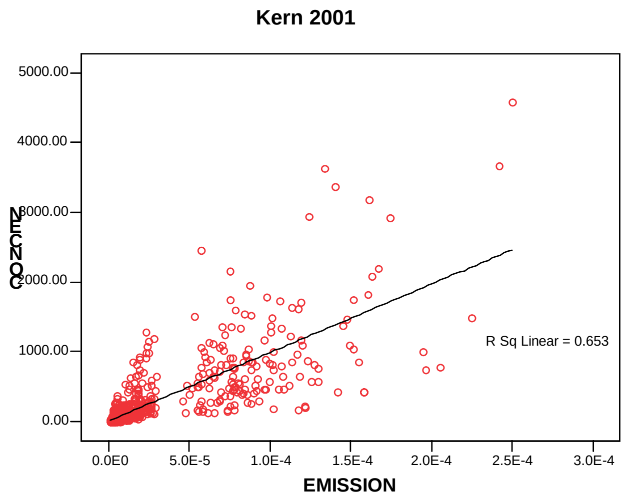
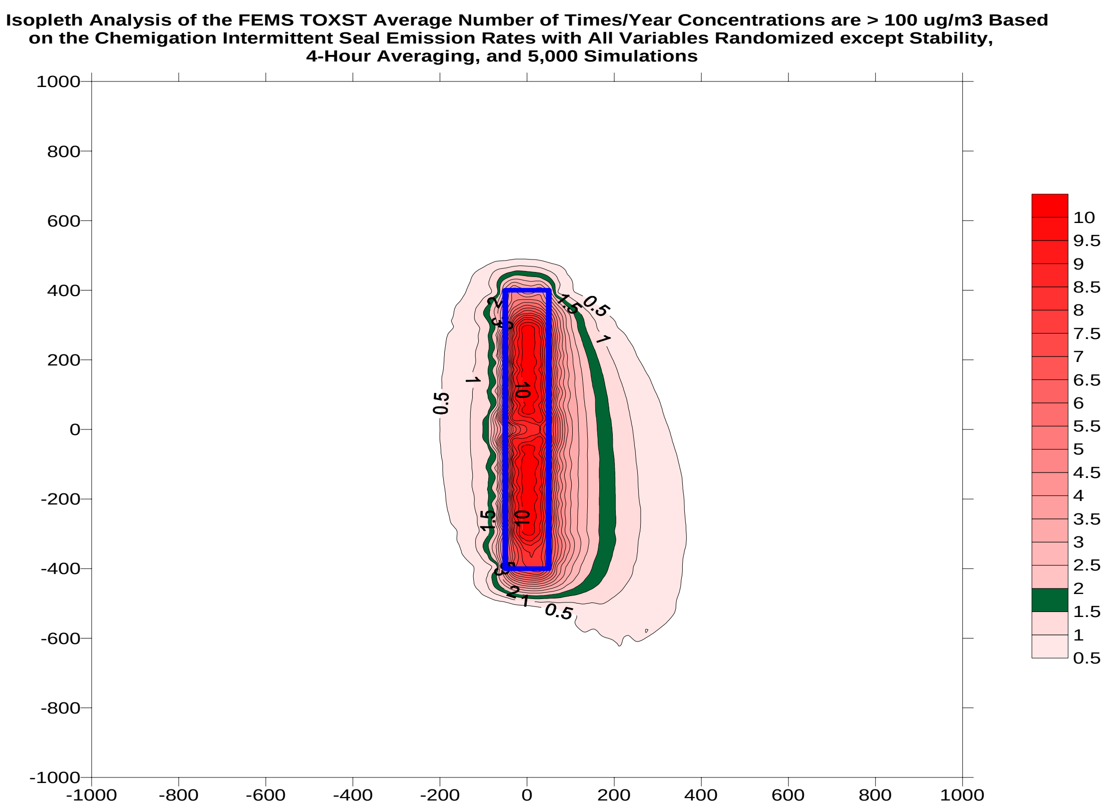


Figure 5



4 CHARGE TO PANEL

This section presents the charge questions the Agency wishes the panel to consider in its deliberations pertaining to FEMS. The nature of these questions are varied and range from issues pertaining to the documentation, design, and operation of FEMS to the manner in which results are presented. For simplicity, the Agency has grouped the questions by subject matter that reflect critical elements pertaining to the use of FEMS and results generated by FEMS. The key subject matter areas include: (1) documentation; (2) system design/inputs; and (3) how results are presented.

Critical Element 1: Documentation

Question 1: The background information presented to the SAP panel by the FEMS developers provides both user guidance and a technical overview of the system. Is this document sufficiently detailed and understandable? Are the descriptions of the specific model components scientifically sound? Do the algorithms in the annotated code perform the functions as defined in this document? Were the panel members able to load the software and evaluate the system including the presented case study?

Critical Element 2: System Design/Inputs

Question 2: In *Section 2.1: Overview of Conceptual Model* of the background document, a series of flowcharts (Figures 2, 3, and 4) are presented that detail the individual processes and components that are included in FEMS. The key processes include (1) emissions processing, (2) 200 year weather inputs and how they are used for longer-term Monte-Carlo sampling; and (3) TOXST analysis. What can the panel say about these proposed processes, the nature of the components included in FEMS and the data needed to generate an analysis using FEMS? Are there any other potential critical sources of data or methodologies that should be considered?

Question 3: The determination of appropriate flux/emission rates is critical to the proper use of the FEMS model as these values define the source of fumigants in the air that can lead to exposures. There are different methods of determining flux/emission rates from empirical data including direct measurements and what is referred to as the "indirect" or "back-calculation" method. Direct measurement of flux is not that common in the available data because of the difficulties and expense associated with generating these types of data. The "indirect" method is most commonly used and involves fitting monitoring data with ISC to determine flux/emission rates. Upon its review of how flux rates can be calculated, the Agency has identified a number of questions it would like the panel to consider. The emission fitting procedures used in FEMS are based on least squares analyses of log-transformed, dispersion modeling and field monitoring data. What, if any refinements are needed for this process? Is it appropriate to log transform these types of data for back-calculation purposes and to use a least-squares regression analysis which implicitly assumes that the fitted line passes through the origin? How appropriate is it to use a flux/emission factor from a single monitoring study (or small number of studies) and apply it to different situations such as for the same crop in a different region of the country? Does the panel believe that FEMS could adequately consider multiple, linked application events as well as single source scenarios? Does FEMS appropriately address situations where data are missing (i.e., is the data filling procedure appropriate)? Should there be a threshold r^2 value below which a regression of measured versus modeled air concentrations should not be used in flux rate determinations? What are possible alternative approaches?

Question 4: The integration of actual time-base meteorological data into ISCST3 is one of the key components that separates the FEMS methodology from that being employed by the Agency in its current assessment. The Agency has identified several potential sources of these data including the National Weather Service, Federal Aviation Administration, California Irrigation Management Information System (CIMIS), and the Florida Automated Weather Network (FAWN). The Agency is also aware that there are several approaches that can be used to process meteorological data and acknowledges that FEMS used PCRAMMET which is a standard Agency tool for this purpose. Upon its review of what meteorological data are available and how it can be processed for use in an assessment such as this, the Agency has identified a number of questions it would like the panel to consider. The test case example in FEMS is based on the National Weather Service ASOS meteorological monitoring station in Fresno, California. What are the SAP's thoughts on the use of National Weather Service / Federal Aviation Administration meteorological data sets in comparison with either CIMIS or FAWN for this type of application? What criteria should be used to identify meteorological regions for analysis and how should specific monitoring data be selected from within each region? Anemometer sampling height has been identified as a concern by the Agency in preparation for this meeting. For example, some data are collected at 2 meters while others are collected at a height of 10 meters. What are the potential impacts of using either type of data in an analysis of this nature? FEMS uses "assumed distributions" to account for uncertainty in the meteorological data based on Hanna, 1998 [as referenced in the FEMS background paper]. Is this an appropriate technique? Does FEMS treat stability class inputs appropriately, especially the quantitative manipulations of these data that have been completed? Is the concurrent use of emissions and meteorological conditions in FEMS useful in identifying concurrent upper-end conditions that could lead to peak exposures for bounding exposure events?

Question 5: The Agency model, ISCST3 is the basis for the FEMS approach. This model has been peer reviewed and is commonly used for regulatory purposes by the Agency. FEMS also uses other Agency systems such as PCRAMMET and TOXST. Are there specific recommendations that the panel can make with regard to any parameter that should be altered to optimize the manner that they are used in FEMS? ISCST3 can treat "calm" (i.e., periods where the windspeed in essentially 0) in one of two ways including the concentration is set to (0) and an approach that uses the last non-calm wind direction/concentration. FEMS uses the first approach. Does the panel concur? In *Section 2.2 Specific Technical Considerations With Regard To The Design Of FEMS* of the background document, there is a section entitled *Computing Endpoint Distances*. Please comment on the procedures included in this section?

The FEMS analysis is based on a single field being treated once per year. On this basis ISCST3 files include 200 full years of hour-by-hour sequential data. Application start times are randomly selected to match the user-supplied application frequency. For example, if a model user entered 10,000 simulations, there will be approximately 10,000 randomly selected start times with batch modeling treatment of 4 days duration for each application. In addition, FEMS allows for more than one application per year to be modeled. Does the panel view this as an appropriate process? If not can it make suggest recommendations or modifications that may improve this process? Can the panel comment on the source geometry used in FEMS and the implications of this choice?

<u>**Critical Element 3: Results**</u>

Question 6: Soil fumigants can be used in different regions of country under different conditions and they can be applied with a variety of equipment. Does the SAP believe that the methodologies in FEMS can be applied generically in order to assess a wide variety of fumigant uses? What considerations with regard to data needs and model inputs should be considered for such an effort?

Question 7: Does FEMS adequately identify and quantify airborne concentrations of soil fumigants that have migrated from treated fields to sensitive receptors? The Agency is particularly concerned about air concentrations in the upper ends of the distribution. Are these results presented in a clear and concise manner that would allow for appropriate characterization of exposures that could occur at such levels?

Question 8: A sensitivity analysis has been conducted and is described in the FEMS background document. What types, if any, of additional contribution/sensitivity analyses are recommended by the panel to be the most useful in making scientifically sound, regulatory decisions? What should be routinely reported as part of a FEMS assessment with respect to inputs and outputs? Are there certain tables and graphs that should be reported? What types of further evaluation steps does the panel recommend for FEMS?